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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/06/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,526

Applicant(s)

Usman

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 21, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10, 15, and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-8 and 17-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Specification

1. Claims 11-14 have been canceled without prejudice towards further prosecution. Claims 9, 10, 15, and 16 have been amended.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the ssRNA" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 9-10 and 15-16 are rejected under 35 U.S.C. 103 (a) over Asher et al. (U.S. Patent 6,214,546 B1) (April 10, 2001) in view of Williams (U.S. Patent 6,255,083 B1) (July 3, 2001).

Asher et al teach a method comprising:

a) contacting:

I) a nucleic acid sensor molecule comprising an enzymatic nucleic acid component and one or more sensor components, wherein in response to an interaction of a single stranded RNA (ssRNA) with the nucleic acid sensor molecule in a system, the enzymatic nucleic acid component catalyzes a chemical reaction on a reporter molecule (either ligation or cleavage of a predetermined RNA molecule) resulting in a detectable response, with

ii) a system comprising at least one ssRNA under conditions suitable for the enzymatic nucleic acid component of the nucleic acid sensor molecule to catalyze a chemical reaction on a reporter molecule resulting in a detectable response (Figures 1-9 and Examples I-III); and

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b) assaying for the chemical reaction resulting in a detectable response (Figures 10-12 and Examples I-III).

Asher et al do not teach a method comprising at least one ssRNA or ssDNA having a SNP.

Williams teaches a method comprising at least one ssRNA or ssDNA having a SNP (Column 2, lines 37-58 and Column 4, lines 24-33).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method comprising at least one ssRNA or ssDNA having a SNP of Williams into the method of Asher et al, since Williams states, "For genotyping the target nucleic acid may be a single nucleotide polymorphism (Column 2, lines 44-46)." Moreover, Asher et al provide further motivation as Asher et al state, "Owing to the catalytic nature of the ribozyme, a single ribozyme molecule cleaves many molecules of target RNA and therefore therapeutical activity is achieved in relatively lower concentrations than those required in an antisense treatment (Column 2, lines 8-12)". Asher et al further state, "The prime utility of the ribozyme detection method of the invention, is within the framework of an assay designed to detect the presence of a biomolecule such as a specific nucleic acid sequence, a member of a binding couple such as antibody-antigen, sugar-lectin, etc., in a biological sample (Column 8, lines 12-17)". By employing scientific reasoning, an ordinary artisan would have combined and substituted a method comprising at least one ssRNA or ssDNA having a SNP of Williams into the method of Asher et al, in order to improve the analysis of a target nucleic acid.

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An ordinary practitioner would have been motivated to combine and substitute a method comprising at least one ssRNA or ssDNA having a SNP of Williams into the method of Asher et al, in order to achieve the express advantages noted by Williams, of an invention that provides the teaching that for genotyping the target nucleic acid may be a single nucleotide polymorphism and also in order to achieve the express advantages noted by Asher et al., of an assay designed to detect the presence of a biomolecule such as a specific nucleic acid sequence, a member of a binding couple such as antibody-antigen, sugar-lectin, etc., in a biological sample .

Response to Amendment

6. In response to amendment, 102(b), 102(e), and 103(a) rejections are hereby withdrawn. However, new 103(a) rejections have been included.

Response to Arguments

7. Applicant's arguments with respect to claims 9, 10, 15, and 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

October 29, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600